

**REMARKS**

Claims 1, 9 and 11-13 are amended and claims 2-3, 6 and 10 are canceled.

**I. Response to Claim Rejections under 35 U.S.C. §112**

Claims 1-3, 6, 7 and 9-15 are rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as being indefinite. The Examiner states that in the definition of R<sup>1</sup> in claim 1, it is not clear whether the cycloalkyl definitions of (1) are intended to be ring substituents attached to the moiety via an alkyl as in the other definitions.

Applicants traverse the rejection.

Definiteness is determined in view of the content of the application disclosure; the teachings of the prior art; and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claim 1 states that R<sup>1</sup> represents (1) a C<sub>5-7</sub> cycloalkyl group optionally fused with a benzene ring.

Applicants submit that the claim language as written is clear and that one of ordinary skill in the art would recognize, based on the plain language of the claim that the cycloalkyl group in (1) of R<sup>1</sup> is directly bonded to the nitrogen atom of the pyrrole ring and not via an alkyl group. This interpretation is also consistent with the working examples provided and the description in the specification, which states at page 20, lines 10-12, "R<sup>1</sup> is preferably (1) a C<sub>5-7</sub> cycloalkyl group optionally fused with a benzene ring (e.g., tetrahydronaphthalenyl, indanyl, etc.)" and at page 21, lines 5-8, that "R<sup>1</sup> is more preferably a C<sub>5-7</sub> cycloalkyl group which may fused with a benzene ring and may be substituted with one or two C<sub>1-4</sub> alkoxy groups (e.g., tetrahydronaphthalenyl, indanyl, etc.) and most preferably, tetrahydronaphthalenyl".

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 1-3, 6, 7, and 9-14 are rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as not being enabled for all hydrocarbons and heterocyclic groups.

Claim 1 is amended herein, thereby obviating the rejection with respect to claim 1 and the claims dependent thereon. Claims 2-3, 6 and 10 are canceled herein, thereby rendering the rejection as to these claims moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 9-15 are rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, as not being enabled for preventing overactive bladder, analgesic or vanilloid receptor agonist activity for all known hydrocarbon and/or all heterocyclic substituted compounds of formula (I).

Claims 9-15 depend directly, or indirectly, from claim 1 and claim 1 is amended as discussed above to further define the compounds of formula (I), thereby obviating the rejection as to claim 1 and its dependent claims, including claim 9-15. Additionally, Applicants note that none of claims 9-15 recite "preventing overactive bladder".

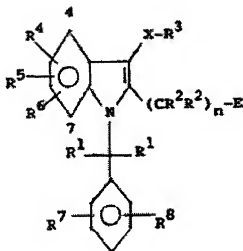
Accordingly, Applicants respectfully request withdrawal of the rejection.

## **II. Response to Claim Rejection under 35 U.S.C. § 103**

Claims 1-13 are rejected under 35 U.S.C. § 103 as being unpatentable over Gillard et al (EP 0275667) in view of Arya et al (US 3,954,757).

Applicants traverse the rejection.

On page 4, Gillard et al (EP-A-0275667) discloses the compound of formula (I) having the following structure:



The structure of this compound is completely different from the present compounds of formula (I) having a condensed ring structure with pyridyl. The compounds of the present invention also have a nitrile group at the position corresponding to X in the compound disclosed by Gillard et al, which is not taught or suggested by Gillard et al.

Additionally, the compounds disclosed by Gillard et al have a different activity than the compounds of the present invention. At page 3, lines 31-54, Gillard et al. discloses that the above compound has activity as leukotriene biosynthesis inhibitors and has the effects described at pages 10-12 of the Amendment filed October 16, 2008.

In contrast, the present invention is based on the finding that the specific pyrrolopyridine derivative has vanilloid receptor agonist activity and is useful as a medicine such as an agent for preventing and/or treating overactive bladder or an analgesic (see the Test Examples in the specification as originally filed).

The activity of the compounds of Gillard et al as leukotriene biosynthesis inhibitors is completely different in mechanism from the vanilloid receptor agonist activity of the compounds of the present invention. Though the effect of the compounds of Gillard et al

partially overlaps with the effect of the present invention because Gillard et al exemplifies pain as a subject disease for anti-inflammatory activity, the basic technical concepts of the respective inventions are completely different from each other. That is, Gillard et al is based on the inhibitory activity of leukotrienes B<sub>4</sub>, C<sub>4</sub>, D<sub>4</sub> and E<sub>4</sub>, which are substances that cause pain, whereas the present invention is based on vanilloid receptor agonist activity.

Thus, based on the structural differences and the disclosure of Gillard et al, one of ordinary skill in the art would not have had a reasonable expectation of success in achieving compounds of the present invention having vanilloid receptor agonist activity.

Arya et al does not remedy the deficiencies of Gillard et al.

Arya et al (US 3,954,757) describes that the disclosed condensed pyrrole mercapto compounds having a specific chemical structure show primarily vasoconstrictor activity in addition to ophthalmological and hypotensive activities, in particular, are useful as a decongestant, e.g., a nasal decongestant (see, column 3, line 63 - column 4, line 4).

Arya et al seems to disclose compounds wherein Ar has a pyridine ring for example at column 1, lines 25-49, but in the Examples, only indol-related compounds are disclosed. There is no Example of a compound having pyrrolopyridine structure in this reference.

Furthermore, Arya et al do not describe the mechanisms of hypotensive and vasoconstrictor activities, and, there is no Test Example demonstrating the pharmacological effects. Thus, one of ordinary skill in the art would not have had a reasonable expectation of success in achieving the present invention based on the disclosure of Arya et al, taken alone or in combination with Gillard et al.

Further, since Arya et al are different from the present invention in not only chemical structure but also in pharmacological effect and use (subject diseases), it is clear that Arya et al

does not teach or suggest the present invention. Thus, even if Gillard et al and Arya et al are combined, they do not teach or suggest the present invention. Also, since their mechanisms are different from that of the present invention, there is no motivation for combining them to arrive at the present invention. Thus, the present invention is patentable over the cited references, whether taken alone or in combination.

Accordingly, Applicants respectfully request withdrawal of the §103 rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

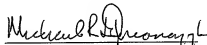
SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: March 17, 2009

  
Michael R. Dzwonczyk  
Registration No. 36,787